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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

LONNY BREYMAN,
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC, (FKA G.D. SEARLE &
CO.),

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:07-cv-04816-CRB
)
) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**
)
) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
 3 ("Searle"), (collectively "Defendants") and file this Answer to Plaintiff's Complaint
 4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
 8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
 9 generally. Defendants may seek leave to amend this Answer when discovery reveals the
 10 specific time periods in which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
 14 Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny
 15 that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain periods
 16 of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
 17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
 18 with their approval by the FDA. Defendants admit that, during certain periods of time,
 19 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
 20 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
 21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 22 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance
 23 with its FDA-approved prescribing information. Defendants state that the potential effects of
 24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
 25 which was at all times adequate and comported with applicable standards of care and law.
 26 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,
 27 and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Hawaii, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States, including Texas and California, to be prescribed by healthcare

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1 providers who are by law authorized to prescribe drugs in accordance with their approval by the
2 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

3 5. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
4 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
5 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
6 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
7 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
8 Celebrex® in the United States to be prescribed by healthcare providers who are by law
9 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
10 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle
11 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
20 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants state that the potential effects of Celebrex® were and are
22 adequately described in its FDA-approved prescribing information, which was at all times
23 adequate and comported with applicable standards of care and law. Defendants deny any
24 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25 7. Defendants state that the allegations in this paragraph of the Complaint regarding
26 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
27 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
28 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

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Response to Allegations Regarding Jurisdiction and Venue

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the State of California and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States, including Hawaii and California, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the States of Hawaii and California. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a tort in the State of Hawaii or the State of California and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Interdistrict Assignment

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants

1 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
2 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
3 Panel on Multidistrict Litigation on September 6, 2005.

4 **Response to Factual Allegations**

5 12. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
8 paragraph of the Complaint.

9 13. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
11 condition or whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state
12 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants state that the potential effects of Celebrex® were and are
14 adequately described in its FDA-approved prescribing information, which was at all times
15 adequate and comported with applicable standards of care and law. Defendants deny that
16 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
17 paragraph of the Complaint.

18 14. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
25 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this
26 paragraph of the Complaint.

27 15. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
2 Celebrex® was expected to reach users and consumers without substantial change from the
3 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 16. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
11 remaining allegations in this paragraph of the Complaint.

12 17. Defendants state that the allegations in this paragraph of the Complaint regarding
13 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no
14 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,
15 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the
16 remaining allegations in this paragraph of the Complaint.

17 18. Defendants state that the allegations in this paragraph of the Complaint are not directed
18 towards Defendants and, therefore, no response is required. To the extent that a response is
19 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
20 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
21 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22 19. Defendants state that the allegations in this paragraph of the Complaint are not directed
23 towards Defendants and, therefore, no response is required. To the extent that a response is
24 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
25 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
26 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27 20. Defendants state that the allegations in this paragraph of the Complaint are not directed
28 towards Defendants and, therefore, no response is required. To the extent that a response is

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1 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
3 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 21. Defendants state that the allegations in this paragraph of the Complaint regarding “other
5 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is
6 required. To the extent a response is deemed required, Defendants state that, as stated in the
7 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to
8 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
9 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
10 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the
11 remaining allegations in this paragraph and Defendants therefore lack sufficient information or
12 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining
13 allegations in this paragraph of the Complaint.

14 22. Defendants state that the allegations in this paragraph of the Complaint regarding
15 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
16 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
17 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
18 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
19 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
20 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants
21 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
22 approved prescribing information. Defendants state that the potential effects of Celebrex®
23 were and are adequately described in its FDA-approved prescribing information, which was at
24 all times adequate and comported with applicable standards of care and law. Defendants deny
25 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
27 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
28 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of

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1 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
2 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
3 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis
4 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny
5 the remaining allegations in this paragraph of the Complaint.

6 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit
7 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
8 Celebrex® in the United States to be prescribed by healthcare providers who are by law
9 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
10 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
12 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
14 and effective when used in accordance with its FDA-approved prescribing information.
15 Defendants state that the potential effects of Celebrex® were and are adequately described in its
16 FDA-approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 25. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
23 this paragraph of the Complaint.

24 26. Defendants state that the referenced article speaks for itself and respectfully refer the
25 Court to the article for its actual language and text. Any attempt to characterize the article is
26 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
28 this paragraph of the Complaint.

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27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 32. Defendants state that the referenced study speaks for itself and respectfully refer the
3 Court to the study for its actual language and text. Any attempt to characterize the study is
4 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
5 paragraph of the Complaint.

6 33. Defendants state that the Medical Officer Review speaks for itself and respectfully refer
7 the Court to the Medical Officer Review for its actual language and text. Any attempt to
8 characterize the Medical Officer Review is denied. Defendants deny any wrongful conduct and
9 deny the remaining allegations in this paragraph of the Complaint.

10 34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
11 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
12 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any
13 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

14 35. Defendants state that the referenced articles speak for themselves and respectfully refer
15 the Court to the articles for their actual language and text. Any attempt to characterize the
16 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
17 refer the Court to the study for its actual language and text. Any attempt to characterize the
18 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 36. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
22 paragraph of the Complaint.

23 37. Defendants state that the referenced articles speak for themselves and respectfully refer
24 the Court to the articles for their actual language and text. Any attempt to characterize the
25 articles is denied. Defendants deny the remaining allegations in this paragraph of the
26 Complaint.

27 38. Defendants state that the referenced article speaks for itself and respectfully refer the
28 Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
2 Court to the study for its actual language and text. Any attempt to characterize the study is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 39. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 40. Plaintiff fails to provide the proper context for the allegations concerning “Public
9 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
10 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 41. Defendants state that the referenced article speaks for itself and respectfully refer the
13 Court to the article for its actual language and text. Any attempt to characterize the article is
14 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 42. Defendants state that the referenced study speaks for itself and respectfully refer the
17 Court to the study for its actual language and text. Any attempt to characterize the study is
18 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public
19 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
20 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 43. Defendants admit that there was a clinical trial called APC. Defendants state that the
23 referenced article speaks for itself and respectfully refer the Court to the article for its actual
24 language and text. Any attempt to characterize the article is denied. Defendants deny the
25 remaining allegations in this paragraph of the Complaint.

26 44. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety

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1 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
2 information or knowledge to form a belief as to the truth of such allegations and, therefore,
3 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 45. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
8 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
9 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 47. Defendants state that the referenced Medical Officer Review speaks for itself and
12 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
13 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
14 allegations in this paragraph of the Complaint.

15 48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
16 the proper context for the allegations concerning “other Celebrex trials” contained in this
17 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
18 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
19 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
20 that the referenced study speaks for itself and respectfully refer the Court to the study for its
21 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
22 remaining allegations in this paragraph of the Complaint.

23 49. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 50. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
27 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
28 therefore lack sufficient information or knowledge to form a belief as to the truth of such

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1 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
2 themselves and respectfully refer the Court to the studies for their actual language and text.
3 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
4 this paragraph of the Complaint.

5 51. Defendants state that the referenced Medical Officer Review speaks for itself and
6 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
7 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
10 are not directed toward Defendants, and therefore no response is required. To the extent that a
11 response is deemed required, Plaintiff fails to provide the proper context for the allegations in
12 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.
13 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
14 such allegations and, therefore, deny the same. Defendants state that the referenced study
15 speaks for itself and respectfully refer the Court to the study for its actual language and text.
16 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in
17 this paragraph of the Complaint.

18 53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
19 Complaint are not directed toward Defendants, and therefore no response is required. To the
20 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
21 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
22 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
23 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
24 referenced study speaks for itself and respectfully refer the Court to the study for its actual
25 language and text. Any attempt to characterize the study is denied. Defendants deny the
26 remaining allegations in this paragraph of the Complaint.

27 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
28 Complaint are not directed toward Defendants, and therefore no response is required. To the

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1 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph
3 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a
4 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the
5 referenced study speaks for itself and respectfully refer the Court to the study for its actual
6 language and text. Any attempt to characterize the study is denied. Defendants state that the
7 referenced article speaks for itself and respectfully refer the Court to the article for its actual
8 language and text. Any attempt to characterize the article is denied. Defendants deny the
9 remaining allegations in this paragraph of the Complaint.

10 55. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants deny the allegations in this
12 paragraph of the Complaint.

13 56. Defendants state that the referenced article speaks for itself and respectfully refer the
14 Court to the article for its actual language and text. Any attempt to characterize the article is
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 57. Defendants state that allegations in this paragraph of the Complaint are not directed
17 toward Defendants, and therefore no response is required. To the extent that a response is
18 deemed required, Defendants state that the referenced article speaks for itself and respectfully
19 refer the Court to the article for its actual language and text. Any attempt to characterize the
20 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 58. Defendants deny the allegations in this paragraph of the Complaint.

22 59. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
27 remaining allegations contained in this paragraph of the Complaint.

28 60. Defendants deny any wrongful conduct and deny the allegations contained in this

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1 paragraph of the Complaint.

2 61. Defendants deny any wrongful conduct and deny the allegations contained in this
3 paragraph of the Complaint.

4 62. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
9 paragraph of the Complaint.

10 63. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
18 the Complaint.

19 64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
20 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
21 November 14, 2000. Defendants state that the referenced letters speak for themselves and
22 respectfully refer the Court to the letters for their actual language and text. Any attempt to
23 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph
24 of the Complaint.

25 65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
26 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
27 the letter for its actual language and text. Any attempt to characterize the letter is denied.
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 66. Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
5 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
6 the letter for its actual language and text. Any attempt to characterize the letter is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 68. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
13 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
15 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
16 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
17 United States to be prescribed by healthcare providers who are by law authorized to prescribe
18 drugs in accordance with their approval by the FDA. Defendants deny the remaining
19 allegations in this paragraph of the Complaint.

20 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
25 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
28 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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1 United States to be prescribed by healthcare providers who are by law authorized to prescribe
2 drugs in accordance with their approval by the FDA. Defendants deny the remaining
3 allegations in this paragraph of the Complaint.

4 72. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which at all times was adequate and comported with applicable standards of care and law.
8 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
9 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
10 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
11 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
12 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
13 United States to be prescribed by healthcare providers who are by law authorized to prescribe
14 drugs in accordance with their approval by the FDA. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 73. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 74. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 75. Defendants deny the allegations in this paragraph of the Complaint.

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1 76. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 77. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 78. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
16 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
17 paragraph of the Complaint.

18 79. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
23 remaining allegations in this paragraph of the Complaint.

24 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® are and were adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® are and were adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
7 the study for its actual language and text. Any attempt to characterize the study is denied.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 83. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® are and were adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint.

20 **Response to First Cause of Action: Negligence**

21 84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
22 Complaint as if fully set forth herein.

23 85. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 admit that they had duties as are imposed by law but deny having breached such duties.
26 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
27 FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 86. Defendants state that this paragraph of the Complaint contains legal contentions to
5 which no response is required. To the extent that a response is deemed required, Defendants
6 admit that they had duties as are imposed by law but deny having breached such duties.
7 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 87. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint, including all subparts.

21 88. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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1 89. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 90. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
14 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
15 paragraph of the Complaint.

16 91. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
18 conditions and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants
19 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny
20 the remaining allegations in this paragraph of the Complaint.

21 92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 93. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Second Cause of Action: Strict Liability**

26 94. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 95. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
2 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
3 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
5 with their approval by the FDA. Defendants admit that, during certain periods of time,
6 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
7 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
8 providers who are by law authorized to prescribe drugs in accordance with their approval by the
9 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
10 consumers without substantial change from the time of sale. Defendants deny the remaining
11 allegations in this paragraph of the Complaint.

12 96. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 97. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
22 remaining allegations in this paragraph of the Complaint.

23 98. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
28 remaining allegations in this paragraph of the Complaint, including all subparts.

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1 99. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
8 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 100. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
15 remaining allegations in this paragraph of the Complaint.

16 101. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
23 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
24 remaining allegations in this paragraph of the Complaint.

25 102. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 103. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
11 paragraph of the Complaint.

12 104. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 105. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Third Cause of Action: Breach of Express Warranty**

5 109. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 110. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants admit that they provided FDA-approved
14 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
15 this paragraph of the Complaint.

16 111. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants admit that they provided FDA-approved
23 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
24 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

25 112. Defendants admit that they provided FDA-approved prescribing information regarding
26 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
27 paragraph of the Complaint.

28 113. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 114. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 115. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants admit that they provided FDA-approved prescribing information regarding
18 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
20 damage, and deny the remaining allegations in this paragraph of the Complaint.

21 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fourth Cause of Action: Breach of Implied Warranty**

26 119. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 120. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed

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1 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
2 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
3 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
4 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
5 Celebrex® in the United States to be prescribed by healthcare providers who are by law
6 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
7 the remaining allegations in this paragraph of the Complaint.

8 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit that they provided FDA-approved prescribing information regarding
13 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 122. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 123. Defendants state that this paragraph of the Complaint contains legal contentions to
20 which no response is required. To the extent that a response is deemed required, Defendants
21 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
22 approved prescribing information. Defendants state that the potential effects of Celebrex®
23 were and are adequately described in its FDA-approved prescribing information, which was at
24 all times adequate and comported with applicable standards of care and law. Defendants deny
25 any wrongful conduct, deny that they breached any warranty, and deny the remaining
26 allegations in this paragraph of the Complaint.

27 124. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
2 medication which is approved by the FDA for the following indications: (1) for relief of the
3 signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid
4 arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of
5 primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
6 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
7 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the
8 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 125. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants admit that they provided FDA-approved
17 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
18 this paragraph of the Complaint.

19 126. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
22 Celebrex® was expected to reach users and consumers without substantial change from the
23 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 127. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they
3 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

4 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 130. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

11 131. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
12 Complaint as if fully set forth herein.

13 132. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is required. To the extent that a response is deemed required, Defendants
15 admit that they had duties as are imposed by law but deny having breached such duties.
16 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 133. Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint, including all subparts.

28 134. Defendants state that Celebrex® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 135. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
13 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this
14 paragraph of the Complaint.

15 136. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 137. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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1 138. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 139. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 140. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 141. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 142. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 145. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Sixth Cause of Action: Unjust Enrichment**

20 146. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 147. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
23 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
24 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
25 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
26 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
27 Celebrex® in the United States to be prescribed by healthcare providers who are by law
28 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny

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1 the remaining allegations in this paragraph of the Complaint.

2 148. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 149. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 150. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 151. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 152. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28

Response to Seventh Cause of Action:

State Consumer Fraud and Deceptive Trade Practices Act

153. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

154. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants deny the remaining allegations in this paragraph of the Complaint.

155. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

157. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

158. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the
2 same. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
7 the Complaint.

8 159. Defendants state that this paragraph of the Complaint contains legal contentions to
9 which no response is required. To the extent that a response is deemed required, Defendants
10 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
11 Complaint.

12 160. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 161. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 162. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 163. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 164. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Eighth Cause of Action: Survival Action**

23 178. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
24 Complaint as if fully set forth herein.

25 179. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 180. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer For Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for Relief,” including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants’ warnings and instructions with respect to the use of

Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product.

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1 Rather, the law requires that all such warnings and appropriate information be given to the
2 prescribing physician and the medical profession, which act as a “learned intermediary” in
3 determining the use of the product. Celebrex® is a prescription medical product, available only
4 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s
5 treating and prescribing physicians.

6 **Thirteenth Defense**

7 13. The product at issue was not in a defective condition or unreasonably dangerous at the
8 time it left the control of the manufacturer or seller.

9 **Fourteenth Defense**

10 14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
11 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
12 the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

13 **Fifteenth Defense**

14 15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the
15 Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable
16 standard of care.

17 **Sixteenth Defense**

18 16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of
19 the product Celebrex® after the product left the control of Defendants and any liability of
20 Defendants is therefore barred.

21 **Seventeenth Defense**

22 17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of
23 Defendants.

24 **Eighteenth Defense**

25 18. Plaintiff’s alleged injuries/damages, if any, were the result of preexisting or subsequent
26 conditions unrelated to Celebrex®.

27 **Nineteenth Defense**

28 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,

the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of

1 Restatement (Second) of Torts § 402A, Comment k.

2 **Twenty-seventh Defense**

3 27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical
4 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
5 to § 6 of the Restatement (Third) of Torts: Products Liability.

6 **Twenty-eighth Defense**

7 28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
8 Products Liability.

9 **Twenty-ninth Defense**

10 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead
11 facts sufficient under the law to justify an award of punitive damages.

12 **Thirtieth Defense**

13 30. Defendants affirmatively aver that the imposition of punitive damages in this case
14 would violate Defendants' rights to procedural due process under both the Fourteenth
15 Amendment of the United States Constitution and the Constitution of the State of California,
16 and would additionally violate Defendants' rights to substantive due process under the
17 Fourteenth Amendment of the United States Constitution.

18 **Thirty-first Defense**

19 31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and
20 Fourteenth Amendments to the United States Constitution.

21 **Thirty-second Defense**

22 32. The imposition of punitive damages in this case would violate the First Amendment to
23 the United States Constitution.

24 **Thirty-third Defense**

25 33. Plaintiff's punitive damage claims are preempted by federal law.

26 **Thirty-fourth Defense**

27 34. In the event that reliance was placed upon Defendants' nonconformance to an express
28 representation, this action is barred as there was no reliance upon representations, if any, of

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Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and

1 proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory
2 damages, if any; (5) permits jury consideration of net worth or other financial information
3 relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial
4 court in post-verdict review of any punitive damages awards; (7) lacks constitutionally
5 sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to
6 satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v.*
7 *Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S.
8 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut.*
9 *Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

10 **Thirty-ninth Defense**

11 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
12 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
13 instructions with respect to the product's use in the package insert and other literature, and
14 conformed to the generally recognized, reasonably available, and reliable state of the
15 knowledge at the time the product was marketed.

16 **Fortieth Defense**

17 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
18 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
19 existing at the time of the sale.

20 **Forty-first Defense**

21 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
22 and belief, such injuries and losses were caused by the actions of persons not having real or
23 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
24 no control and for whom Defendants may not be held accountable.

25 **Forty-second Defense**

26 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
27 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
28 intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from

1 collateral sources.

2 **Fifty-first Defense**

3 51. Defendants' liability, if any, can only be determined after the percentages of
4 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
5 any, are determined. Defendants seek an adjudication of the percentage of fault of the
6 claimants and each and every other person whose fault could have contributed to the alleged
7 injuries and damages, if any, of Plaintiff.

8 **Fifty-second Defense**

9 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
10 common law gives deference to discretionary actions by the United States Food and Drug
11 Administration under the Federal Food, Drug, and Cosmetic Act.

12 **Fifty-third Defense**

13 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
14 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
15 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
16 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
17 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
18 and with the specific determinations by FDA specifying the language that should be used in the
19 labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the
20 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
21 United States.

22 **Fifty-fourth Defense**

23 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
24 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

25 **Fifty-fifth Defense**

26 55. Defendants state on information and belief that the Complaint and each purported cause
27 of action contained therein is barred by the statutes of limitations contained in California Code
28 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation

as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

November 8, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

November 8, 2007

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